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Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,425,892 was filed on July 19, 2006, under 35 U.S.C. § 156. Another application for patent term extension based on the regulatory review period of IONSYS™ was filed for U.S. Patent No. 5,697,896.

The assistance of your Office is requested in confirming that the product identified in the application, IONSYS™ (fentanyl iontophoretic transdermal system), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be NOT eligible for extension of the patent term under 35 U.S.C. § 156 because the base form of fentanyl was previously approved as a human drug under 21 U.S.C. § 355 (section 505 of the Federal Food, Drug and Cosmetic Act) and the present approval is an approval of a salt form of fentanyl, namely, fentanyl hydrochloride.

At issue in this case is whether the approval of the New Drug Application (NDA) for IONSYS™ (fentanyl iontophoretic transdermal system), which according to Applicant was granted by the FDA on May 22, 2006, constitutes the first permitted commercial marketing or use of the product in accordance with § 156.

The definition of product is defined in 35 U.S.C. 156(f), which states:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product.
> . . .
> (2) The term "drug product" means the active ingredient of—
> (A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act)
> . . .
> including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

Since a drug product means the active ingredient of the new drug and includes any salt or ester of the active ingredient, the present approval does not appear to constitute the first permitted commercial marketing or use of the approved product as the term "product" is defined in 35

U.S.C. 156. Specifically, the drug product in IONSYS™, fentanyl hydrochloride, is a salt of the active ingredient in Duragesic®, fentanyl. Therefore, the previous approval of the drug product Duragesic® having the active ingredient fentanyl would mean that approval of the product, IONSYS™, an iontophorteic device containing fentanyl hydrochloride as an active ingredient, would NOT constitute the first permitted commercial marketing or use of the active ingredient fentanyl as fentanyl was previously approved in Duragesic®. Moreover, Applicants admit that fentanyl was previously approved as Duragesic® on page 4 of their application for patent term extension.. Additionally, review of the electronic Orange Book indicates that fentanyl was previously approved under section 505 of the Federal Food Drug and Cosmetic Act as Duragesic®.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Philip S. Yip
ALZA Corporation
c/o Johnson & Johnson
One Johnson & Johnson Plaza, WH 3221
New Brunswick, NJ 08933

Enclosure: Copy of Electronic Orange Book listing for fentanyl, found at:
http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm, accessed on November 3, 2006.